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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/912,947	07/25/2001	Bjorn Dahlback	INL-036DV 7730		
21323 7	7590 03/29/2005		EXAMINER		
TESTA, HUF	RWITZ & THIBEAU	WHISENANT, ETHAN C			
HIGH STREE			ART UNIT	PAPER NUMBER	
BOSTON, MA 02110			1634		
			DATE MAIL ED: 03/20/2005		

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary Examiner			Application No	 D.	Applicant(s)				
Ethan Whisenant, Ph.D. 1634 Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. If the period for reply specified store is less than thing (30) days, and the correspondence address—are SK (30) days, and the correspondence of the correspondence is seen than thing (30) days, and the correspondence of the correspond	Office Action Summary		•	:					
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Non-Final Rejection

- 1. The applicant's Response (filed 08 DEC 04) has been entered. Following the entry of the claim amendments Claim(s) 1-45, 49, 53-63 is/are pending. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.
- 2. Please note that this application has been transferred to a different examiner within Art Unit 1634. See the closing pagragraph of this action for details.

PRIORITY

3. The applicant's Supplemental ADS have been entered and the applicant's claim(s) to foreign and/or domestic priority is confirmed.

SPECIFICATION

4. The specification has been amended as directed.

35 USC § 112- 2ND PARAGRAPH

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH

6. Claim(s) 54-63 is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 54 is indefinite because the phrase "the Factor V gene locus" lacks proper antecedent basis.

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35 USC § 112 - 1ST PARAGRAPH

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

CLAIM REJECTIONS under 35 USC § 112- 1st PARAGRAPH

8. Claim(s) 46, 49 and 53-63 is/are rejected under 35 U.S.C. 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected to make the invention commensurate in scope with these claims without undue experimentation.

The reasoning for the enablement rejection has been presented in earlier office actions.

Response to applicant's Amendment and/or Arguments

9. Applicant's arguments regarding the 35 USC 112, 1st paragraph rejections have been fully and carefully considered, however, are deemed not to be persuasive. The applicant again traverses the enablement rejection.

In response to the applicant applicant arguments. The examiner respectfully asserts that the applicant has not conclusively shown that a mutated Factor V gene is: the cause of an increased risk of developing thrombosis in an individual / associated with APC-resistance. The evidence presented simply indicate that the Factor V gene is most likely involved but does not provide conclusive evidence of Factor V gene involvement. Although we now know that the applicant was correct in asserting that a mutation in the Factor V gene is the cause of APC-resistance, see Bertina et al. [US 6,518,016 (2003)], at the time of the applicant's disclosure this was not know. It is possible that the genetic defect leading to APC-resistance was the result of a defect in some other unknown gene physically close to the Factor V gene. Without showing the exact defect leading to APC-resistance the disclosure simply leads to additional experimentation in order to discover ther true defect leading to APC-resistance. Accordingly, the examiner continues to assert that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected to make the invention commensurate in scope with these claims without undue experimentation. As regards the applicants position that the examiner should not use post-filing date references to demonstrate that the patent is non-enabling." The MPEP does provide for exceptions to that "rule". "Exceptions to this rule could occur if a later-dated reference

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provides evidence of what one skilled in the art would have known on or before the effective filing date of the patent application. In re Hogan, 559 F.2d 595, 605, 194 USPQ 527, 537 (CCPA 1977). If individuals of skill in the art state that a particular invention is not possible years after the filing date, that would be evidence that the disclosed invention was not possible at the time of filing and should be considered. In In re Wright, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513-14 (Fed. Cir. 1993) an article published 5 years after the filing date of the application adequately supported the examiner's position that the physiological activity of certain viruses was sufficiently unpredictable so that a person skilled in the art would not have believed that the success with one virus and one animal could be extrapolated successfully to all viruses with all living organisms. Claims not directed to the specific virus and the specific animal were held nonenabled." See MPEP 2164.05(a).

CONCLUSION

- 10. Claim(s) 46, 49, 53-63 is/are rejected and/or objected to for the reason(s) set forth above.
- 11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (571) 272-0745.

The fax number for this Examiner is (571) 273-0754. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

ETHAN WHISENANT PRIMARY EXAMINER

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